

REMARKS

The Examiner's attention to the present application is noted with appreciation.

Claim Rejections – 35 U.S.C. § 112.

Claim 31 is amended to refer to "at least one cavity."

Claim 39 is amended to make clear the antecedent basis for "the inlet end of a microfluidic channel."

Claim 44 is amended to depend on claim 43.

Claim Rejections – 35 U.S.C. § 103.

*Rejection based on Mathies et al. in view of Wang et al.* Claims 1-7, 9-20, 25-34, and 36-63 are rejected. The rejection is traversed for the reasons set forth herein.

Claims 1 (apparatus) and 39 (method) are independent claims. The Office Action rejects claims 1 and 39 on "two different interpretations of the edge of the substrate" with reference to the Mathies et al. reference. First, reference is made to Fig. 20 where an "outlet end of the channel **46** is formed at one edge of the substrate; being formed at an edge does not require the channel to pass through the edge of the substrate." Second, it is alternatively suggested that Mathies et al. discloses that the outlet end of the channel terminates in a reservoir, "which forms an inner edge of the substrate (Figs. 18 and 20)." With all due deference, it is submitted that the "interpretations" are strained, ignore the teachings of the specification and are not permissible under the language of the claims.

As previously amended, claim 1 provides "a first substrate having at least one edge" and an elongated separation channel having "an outlet end at the at least one edge." The structure is further defined by the last limitation, providing "at least one thick-film electrode for analyte detection on the second substrate, the thick-film electrode being in fluidic connection with the outlet end of the separation channel."

Applicant submits that neither interpretation is proper given the disclosure of the specification and drawings, and the remainder of the claims. However, in order to expedite allowance of the case, claims 1 and 39 are amended to make clear that the outlet "transits" an "exterior" edge of the first substrate. In this context, "transit" is used as ordinarily defined: to pass over or through. See, e.g., Webster's New Collegiate Dictionary, 1974. It is submitted that this amendment fully addresses the rejection. The word "transits" requires the channel to pass through the edge. Similarly, the word "exterior" excludes an "inner edge." Given that claims 1 and 39 are thus allowable, it follows that the dependent claims are similarly allowable.

Regarding claim 34, it is noted that where the "second substrate is at an angle to the first substrate" this excludes a parallel or 0° angle. An angle, as conventionally understood, is a "figure formed by two lines extending from the same point or by two surfaces diverging from the same line." Webster's New Collegiate Dictionary, 1974. This is clearly the usage contemplated in the claims and specification. Parallel lines, by definition, do not intersect. Note that claim 36 (parallel) is not dependent from claim 34 (angle), but rather is dependent from claim 1. Note also that the interpretation suggested in the Office Action would render the limitation "at an angle" a nullity; if "at an angle" encompasses parallel substrates, then it adds nothing: the logical possibilities are only parallel substrates (i.e., co-planar) or substrates at a non-zero angle to each other.

Rejections of claims 8 and 21 relying on Dubrow et al., are addressed in the discussion relating to claim 64.

*Rejection based on Mathies et al. in view of Wang et al. and further in view of Dubrow et al.*

Claims 64, 65 and 67-84 are rejected. The rejection is traversed for the reasons set forth herein.

Claim 64 contains a specific limitation providing "a second substrate removably positionable with respect to the first substrate." Claim 64 further contains a specific limitation providing "at least one thick-film electrode for analyte detection disposed on the second substrate, the thick-film electrode being in fluidic connection with the outlet end of the separation channel." As the Office Action acknowledges,

Mathies et al., discloses a "second substrate (top plate) **14** bonded to the first substrate **11**." Dubrow et al. is cited for the proposition that a "second substrate **102** may be bonded to the first substrate **110**, or the substrates may be detachably connected using a clamping system." However, the second substrate **102** of Dubrow et al. is solely a cover that "includes a plurality of ports **106**" that are "positioned to communicate with specific points of the channels or grooves..." (Dubrow et al., col. 4, lines 18-26). There is no teaching or suggestion in Dubrow et al. of any electrode of any type, much less a thick-film electrode. Indeed, Dubrow et al. teach away from an electrode by including an "optical detection window **116**" in the disclosed microfluidic devices. Col. 4, lines 27-39.

As *In re Lee*, 277 F.3d 1338, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002) makes explicit, there must be "a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness." 277 F.3d at 1343. This test is predicated on the need to avoid "hindsight-based obviousness analysis." Thus there must be "particular findings" as to why an artisan, with no knowledge of the claimed invention, would have selected the components for combination in the manner claimed. This requires either "some objective teaching in the prior art" or "knowledge generally available to one of ordinary skill" that would motivate and lead one to combine the references. Id.

The sole discussion on the combination with Dubrow et al., is at pages 14 and 15 of the Office Action, with the argument in support of obviousness being that "a detachable connection allows the cover to be removed from the substrate containing the channels." This statement merely reiterates the invention in the guise of "obviousness." Of course, a "detachable connection" allows a cover to be removed. This does not point to any "objective teaching in the prior art" or "knowledge generally available" as to why a cover with ports can be combined with art related to detection using thick-film electrodes.

More important, the combination of Dubrow et al., with other prior art would not result in the invention of claim 64. As the Office Action acknowledges, Dubrow et al., provide a "cover" which literally covers the channels; *i.e.*, the "cover" forms a boundary for the channels and/or wells. See Dubrow et al., at Col. 3, lines 23-32. This is not the function of the "second substrate" of claim 64. No limitation of

claim 64 requires that it be "co-planar" with the first substrate; indeed, claims 65 and 66 make clear that the first substrate and second substrate need not be co-planar or parallel. No limitation in claim 64 requires that the second substrate form a boundary for the channels and/or wells. Further, claim 64 provides additional structure for the second substrate: at least one thick-film electrode, which must be in fluidic connection with the outlet. In summary, Dubrow et al., merely provide a cover, which must necessarily be co-planar with substrate with microseparation channels, and which forms a "top" for the microseparation channels. The cover has holes, providing access to the channels or wells. Dubrow et al., do not mention or suggest electrochemical detection using a thick-film electrode; the sole detection means is optical detection. By contrast, in claim 64 the second substrate does not form a cover, and is not required to form a "top" for separation channels. Rather its function is entirely different: to hold and position one or more thick-film electrodes with respect to outlets of separation channels.

Under any analysis, the invention of claim 64 is not obvious over Dubrow et al., and the other cited references. The "second substrate" of claim 64 is not analogous to the "cover" of Dubrow et al., the combination would be inoperative (a cover would not position a thick-film electrode as required in claim 64), and there is no motivation or suggestion, other than hindsight, as to why a teaching about removable covers with access ports should be combined with an invention involving a removably positionable second substrate for positioning a thick-film electrode in relation ("fluidic connection") to the outlet end of a separation channel.

Because claim 64 is allowable, it follows that the remaining dependent claims are similarly allowable. Applicant reiterates its argument relating to "at an angle" as to claim 65; "at an angle" clearly means "not parallel", and thus excludes a "zero degree angle."

#### Conclusion

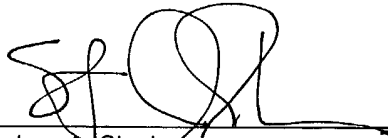
An earnest attempt has been made to respond to each and every ground of rejection advanced by the Examiner. However, should the Examiner have any queries, suggestions or comments relating to a speedy disposition of the application, the Examiner is invited to call the undersigned.

Also being filed herewith is a Petition for Extension of Time to June 2, 2004, with the appropriate fee.

Reconsideration and allowance are respectfully requested.

Respectfully submitted,

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